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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,940	08/31/2001	Han-Mo Koo	38345-174995	8963

26694 7590 10/20/2005  
VENABLE LLP  
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EXAMINER

DAVIS, MINH TAM B

ART UNIT PAPER NUMBER

1642

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/942,940

Applicant(s)

KOO ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-12, 14-18,20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,8,11,12,17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5-7,9,10,14-16,20 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claims 4, 13, 19.

Accordingly, claims 1, 5-7, 9-10, 14-16, 20-21 are being examined.

It is noted that the embodiment of claim 16, drawn to a method for inhibiting growth or recurrent growth of melanoma tumor in a mammal "at risk for melanoma growth or recurrence" has been withdrawn from consideration as being drawn to non-elected invention.

The following are the remaining rejections.

### **REJECTION UNDER 35 USC 103**

Claims 1, 5-7, 9-10, 14-16, 20-21 remain rejected under 35 USC 103 as being obvious over Shellman Y et al, April 2000, J Investigative Dermatology, 114(4): 789, in view of US 6,147,107, Sebolt-Leopold JS et al, 1999, Nature Medicine, 5(7): 810-816, and Hoshino, R, et al, 1999, Oncogene, 18: 813-822, for reasons already of record in paper of 01/27/05.

Applicant argues that nothing in the art suggests or teaches that one combines in a single anti-melanoma treatment, two different MEK inhibitors of the class to which PD98059 and PD184352 belong.

Art Unit: 1642

Applicant argues that the method of killing melanoma cells or treating melanoma, by using any of the combination of PD98059 or PD184352 with UO126 or any other MEK inhibitor, and cisplatin or any compound would not be obvious over Shellman et al.

Applicant arguments in paper of 08/09/05 have been considered but are found not to be persuasive for the following reasons:

Due to the open language "comprising" of claim 1, 9, 16, the claims are not limited to a single step of contacting melanoma cells or administering a composition consisting of the MEK inhibitor PD98059 or PD184352.

In other words, the claims encompass a method for treating melanoma comprising administering a composition consisting of the MEK inhibitor PD98059 or PD184352 taught by US 6,147,107 or Sebolt-Leopold et al, wherein said treatment could have an additional step, such as administering of cisplatin, or administering a composition comprising multiple inhibitors of Ras, P13K, MEK and NF-kB, that increases spontaneous melanoma cell apoptosis, or cisplatin induced apoptosis, as taught by Shellman et al.

It would have been obvious to administer to melanoma patients the MEK inhibitor PD98059 or PD184352, because PD98059 or PD184352 taught by US 6,147,107 or Sebolt-Leopold et al is known to suppress growth of other cancers such as carcinoma or colon cancer via the MEK pathway, and because the MAP kinase of the MEK pathway is activated in several human cancers, including skin cancer cell line, as taught by Hoshino et al.

Further, it would have been obvious to add an additional step, such as administering of cisplatin, or administering a composition comprising multiple inhibitors of Ras, P13K, MEK and NF-kB, taught by Shellman et al, to ensure the killing of melanoma cells, because said composition taught by Shellman et al increases spontaneous melanoma cell apoptosis, or cisplatin induced apoptosis, as taught by Shellman et al, and because anti-apoptotic defense of melanoma are regulated through multiple signaling pathways, including Ras, P13K, MEK and NF-kB, as taught by Shellman et al.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

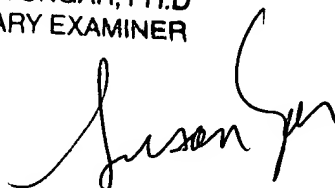
Art Unit: 1642

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS  
October 12, 2005

SUSAN UNGAR, PH.D  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "Susan Ungar", with a stylized flourish at the end.